PROVIDER BULLETIN

No 10-12

April 5, 2010

TO: Medicaid Providers of Injectable Psychiatric Medications

FROM: Vivianne M. Chaumont, Director
Division of Medicaid and Long-Term Care

BY: Bonnie Brown, R.N.
Mental Health and Substance Abuse Unit

RE: Prior Authorization for Invega Sustenna and Vivitrol

Please share this information with administrative, clinical, and billing staff

Invega Sustenna and Vivitrol injections must be prior authorized through Magellan Health Services for all clients. Magellan may be contacted at 1-800-424-0333.

Prior authorization is required for Medicaid clients receiving either managed care or non-managed care benefits. Prior authorization is required whether services are being provided in an outpatient community based clinic or in an outpatient hospital-based program.

Reimbursement will be based on the provider's cost (471 NAC 18-004.28) as documented on an invoice. The invoice must include the provider's name and Medicaid number, the client's name and Medicaid number, the date of service and number of units. Fax the invoice to Bonnie Brown at (402) 471-9092 for the invoice cost to be loaded. Once the first invoice cost is loaded, new invoices are only required when the provider's cost either decreases or increases.

The claim form must include the Magellan prior authorization number, appropriate HCPCS procedure code, number of units per HCPCS description, correct National/Drug Code (NDC), NDC 'unit of measure' and number of NDC units. A CPT code for the administration must also be submitted on the same claim.

For Prior Authorization questions, contact Magellan at 1-800-424-0333. For billing questions, call or e-mail Bonnie Brown at (402) 471-1611 or bonnie.brown©nebraska.gpv.

Attachments:
- Clinical Guidelines: Vivitrol
- Medical Necessity Form: Vivitrol
- Clinical Guidelines: INVEGA SUSTENNA

Clinical Guidelines: Vivitrol

The FDA has approved naltrexone extended-release injectable suspension (*Vivitrol*) for the treatment of alcohol dependence in patients who are able to abstain from drinking in an outpatient setting, and who are not actively drinking when treatment with Vivitrol is started. The effects of Vivitrol cannot be reversed, and last up to a month, or longer, therefore it is essential to identify any potential for an adverse reaction, before the first use of Vivitrol.

Authorization must be obtained prior to instituting treatment with Vivitrol.

Admission Guidelines

All of the following guidelines must be met:

1. Client has been diagnosed with Alcohol Dependence, based on the criteria in the current edition of the DSM.
2. Client has demonstrated an ability to remain abstinent from alcohol in the community. Abstinence during treatment in a residential setting, or during incarceration, is not sufficient to meet this requirement. The client must be abstinent from alcohol for at least 3 weeks prior to the first planned dose.
3. Although Vivitrol is not a treatment for opioid dependence, clients must be free of all opioid use, from any source, for a minimum of 7-10 days before the first injection, and must continue to remain abstinent from opioids throughout the duration of treatment. Client should not be in acute opiate withdrawal when Vivitrol is injected.
4. Client does not require prescribed opioid medications for treatment of a medical condition.
5. Client has had a recent drug screen [urine and/or blood] that is negative for alcohol, opioids, and illicit drugs, and written documentation has been submitted.
6. Client has signed an informed consent, which includes the information that there may be a risk of serious medical complications associated with Vivitrol, the injectable form of naltrexone, that have not been observed when the tablet form is used.
7. Client has had a recent, comprehensive History and Physical Examination [H&P], specifically for the purpose of obtaining medical clearance to begin treatment with Vivitrol, and the results have been submitted.
8. Client's H&P states that, based on examination and laboratory testing, the client does not have any medical conditions, including reduced liver or renal functions, a respiratory disorder, or a digestive tract disorder that would make the use of Vivitrol potentially unsafe. The H&P includes the statement that the examiner has medically cleared the client to begin Vivitrol injections.
9. Client is physically unable to take any oral medications, or oral medications are medically contraindicated, and written documentation has been submitted.
10. Client has signed an agreement to participate in a comprehensive substance abuse treatment program while receiving Vivitrol.

Exclusion Guideline

If any of the following are met, Vivitrol cannot be authorized:

1. Client is under 18 years of age
2. Client is pregnant, or may become pregnant, during treatment with Vivitrol. Client is breastfeeding.
3. Client is physically dependent upon opioids. Vivitrol will cause the rapid onset of acute withdrawal from opioids. Attempts to relieve the symptoms of withdrawal, or to obtain the usual opioid effects, by taking larger doses than usual may be fatal.
4. Client requires opioid containing medications, either occasionally or on an ongoing basis, for medical treatment. Examples include pain management, control of diarrhea, or as a cough suppressant.
5. Client has no medical contraindications that prevent taking oral naltrexone.
6. Client's drug screen [urine and/or blood] is positive for alcohol, opioids or any illicit drugs, or client fails a naltrexone challenge test.
7. Client is not currently compliant with the required comprehensive substance abuse treatment program.

Continuing Stay Guidelines

All of the following must be met:

1. Client continues to meet admission guidelines for Vivitrol, and none of the exclusions apply.
2. Client is participating in a substance abuse treatment program, and there is evidence of progress, as well as documentation that Vivitrol continues to be required, in order for the client to meet treatment goals.
3. Vivitrol continues to be used as part of an active treatment plan to treat Alcohol Dependence and is not intended for long term, or maintenance use.
4. Medical necessity for continuing Vivitrol must be re-evaluated at least every three months, to determine continued need for Vivitrol.

Discharge Guidelines

Vivitrol will no longer be authorized when one or more of the following are met:

1. Client is experiencing adverse side effects and/or there is a medical reason to discontinue Vivitrol.
2. Client is able to use the oral form of naltrexone.
3. Vivitrol is no longer a necessary part of the client's overall substance abuse treatment plan, either because of the client's successful abstinence from alcohol, or because Vivitrol has not been effective for the treatment goal of abstinence.

02-22-10

MAGELLAN
HEALTH SERVICES
Getting Better All the Time

Vivitrol Injection (All requests must be approved in advance to insure authorization)

Fax to Magellan: **888-656-4919** Today's Date: _____

Provider: _____ Contact: _____

Phone Number: _____ MIS #: _____

Address: _____ Member Name: _____

Medicaid Managed Care #: _____

Dx: Axis I: _____

Axis II: _____

Axis III: _____

Axis IV: _____

Axis V Current GAF: _____ Past Year: _____

Guidelines for Approval (See posted guidelines for complete version)

1. Client has been diagnosed with Alcohol Dependence: _____
2. The client must be abstinent from alcohol for at least 3 weeks prior to the first planned dose: _____
3. Although Vivitrol is not a treatment for opioid dependence, clients must be free of all opioid use, from any source, for a minimum of 7-10 days before the first injection: _____
4. Client does not require prescribed opioid medications for treatment of a medical condition: _____
5. Client has had a recent drug screen [urine and/or blood] that is negative for alcohol, opioids, and illicit drugs: _____
6. Medical clearance to begin treatment with Vivitrol: _____
7. Client is physically unable to take any oral medications, or oral medications are medically contraindicated: _____
8. Client has signed an agreement to participate in a comprehensive substance abuse treatment program while receiving Vivitrol: _____

Exclusion Guideline

Vivitrol *will not be authorized if any of the following are true:*

1. Client is under 18 years of age
2. Client is pregnant or may become pregnant during treatment with Vivitrol. Client is breastfeeding.
3. Client is physically dependent upon opioids. Vivitrol will cause rapid onset of acute withdrawal from opioids. Attempts to obtain the usual opioid effects by taking larger doses than usual may be fatal.
4. Client requires opioid containing medications, either occasionally or on an ongoing basis, for medical treatment. Examples include pain management, control of diarrhea, or as a cough suppressant.
5. Client has no medical contraindications to oral naltrexone.
6. Client's drug screen [urine and/or blood] is positive for alcohol, opioids or any illicit drugs, or client fails a naltrexone challenge test.
7. Client is not compliant with the required comprehensive substance abuse treatment.

Continuing Stay Guidelines

All of the following must be met

1. Client continues to meet admission guidelines for Vivitrol, and none of the exclusions apply.
2. Client is participating in a substance abuse management program, and there is evidence of progress, as well as documentation that Vivitrol continues to be required, in order for the client to meet treatment goals.
3. Vivitrol continues to be used as part of an active program to treat Alcohol Dependence and is not intended for long term, or maintenance use. Medical necessity for continuing Vivitrol must be re-evaluated at least every three months, to determine continued need for Vivitrol.

Discharge Guidelines

Vivitrol will no longer be authorized when one or more of the following are met

1. Client is experiencing adverse side effects and/or there is a medical reason to discontinue Vivitrol.
2. Client is able to use the oral form of naltrexone.
3. Vivitrol is no longer an integral part of the client's overall substance abuse treatment program, either because of the client's successful abstinence from alcohol, or because Vivitrol has not been effective for the treatment goal of abstinence.

Please extend authorization for _____ months or _____ injections.

Dosage given on each appointment date: _____ (mg)

Dates of injections: _____; _____; _____; _____; _____; _____

J_____ (Vivitrol) x _____ Units
96372 (injection) x _____ (number of injections)

Authorization #: _____

☐ Please Fax this Form with the authorization # back to Provider: _____
☐ Please call us back with authorization #

Clinical Guidelines: INVEGA SUSTENNA

INVEGA SUSTENNA is a long-acting injectable medication that has been FDA approved for the treatment of Schizophrenia. INVEGA SUSTENNA is reserved for use only in cases where this alternative to oral medication is necessary.

Guidelines for Use

All of the following must be met before INVEGA SUSTENNA will be authorized:

1. The client has a DSM diagnosis of Schizophrenia.
2. The client's ability to tolerate extended exposure to this medication must be established, by the use of oral Invega, prior to the first injection of INVEGA SUSTENNA.
3. There is clear documentation that the client cannot take oral Risperdal (including Risperdal M-Tabs), oral Invega or Risperdal Consta. Documentation should include the dose(s) of these oral medications, the start and end dates they were prescribed, and the reason why INVEGA SUSTENNA is expected to be effective, even though oral Risperdal, oral Invega or Risperdal Consta were not.
4. There is clear documentation that the client cannot be treated with Haldol Decanoate, Prolixin Decanoate or Risperdal Consta. Documentation should include the dosages, the frequency of injection, the length of time each of these depot neuroleptics were prescribed, and the reason that none of them is safe and/or effective for the client.
5. There is clear documentation that the client has been prescribed several oral antipsychotic medications, but could not be safely and effectively treated with any of those medications. Documentation should include the appropriate detailed information, as described above.
6. The client has agreed to receive the injections on a regular basis, at the interval prescribed, and a person or agency that is geographically accessible and capable of dispensing the injections at the required frequency has been identified.
7. The maximum FDA approved dosage is 234 mg every month. Amounts in excess of this dose and frequency will not be authorized.

Exclusion Guidelines

INVEGA SUSTENNA will not be authorized if any of the following are true:

1. The client is under 18 years of age.
2. More than one provider is prescribing antipsychotic medication to the client.
3. INVEGA SUSTENNA has been prescribed because it is more convenient for staff or caregivers.

Continuing Stay Guidelines

Met, when all of the following are true:

1. The client continues to meet the admission guidelines for INVEGA SUSTENNA

Discharge Guidelines

Met, when one, or both, of the following are true:

1. INVEGA SUSTENNA is no longer prescribed for the client.
2. The client withdraws consent for INVEGA SUSTENNA.

03-17-2010